

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA**

NATERA, INC.,

Plaintiff,

v.

NEOGENOMICS LABORATORIES,
INC.,

Defendant.

C.A. No. 1:23-CV-629-CCE-JLW

**DECLARATION OF TIM FORSHEW, PH.D. IN SUPPORT OF NEOGENOMICS
LABORATORIES, INC.'S OPPOSITION TO NATERA, INC.'S MOTION TO
EXCLUDE NEOGENOMICS LABORATORIES, INC.'S SUPPLEMENTAL
INTERROGATORY RESPONSES AND TO PRECLUDE REFERENCE TO CERTAIN
INFORMATION**

I, Tim Forshew, declare as follows:

I. Background and Experience

1. I am a co-founder of Inivata Limited and serve as the Head of Science and Innovation at NeoGenomics Laboratories, Inc. During my time at NeoGenomics, I have worked on research and development of technologies for minimum residual disease (“MRD”) in cancer patients including NeoGenomics’ RaDaR product as well as other liquid biopsy technologies.

2. I received a Ph.D in Genetics in 2004 from the University of Birmingham where I studied the mapping of genes responsible for rare recessive eye disorders under the supervision of Professor Eamonn Maher.

3. From 2006 to 2010, I was a postdoctoral research fellow at Barts and The London School of Medicine and Dentistry where my primary focus of research was to investigate the genetics and epigenetics of childhood brain tumours.

4. From 2010-2014, I worked at the Cancer Research UK Cambridge Institute at the University of Cambridge as a postdoctoral research fellow and then a senior research associate. During this time, I worked in the Rosenfeld laboratory where the primary goal of our group was to develop diagnostic strategies by combining molecular technologies with computational and genomic approaches. In particular, my work entailed exploring the diagnostic potential of cell free tumour DNA. The main focus of my research was the development of next generation sequencing methods for rare mutation detection.

5. In September 2014, I co-founded Inivata Limited, which has since been acquired by NeoGenomics Laboratories, Inc. I served as a Technical Advisor from September 2014 to May 2015, the Head of Technology Development from June 2015 to August 2017, and have served as the Head of Science and Innovation since August 2017.

6. In addition to my work at Inivata, from 2014 to 2016, I was a group leader at University College London where I established a new translational cancer genetics group. Our team worked on genetic approaches in an attempt to both improve our understanding of cancer and how best to treat patients. I have served as an honorary lecturer at University College London from time to time on the topic of genetics and next generation sequencing technologies.

7. I was deposed in this case on July 19, 2024. I understand I was designated as the corporate witness regarding several topics, including Topic 51 and 52 regarding the design, development, and costs of [REDACTED]

II. Assay Development

8. Development of a new assay at NeoGenomics entails the following stages:

9. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

10. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹ A Laboratory Information Management System (LIMS) is a software platform that digitally records and tracks metadata, results, workflows, and instruments associated with lab samples.

11. [REDACTED]

[REDACTED]

[REDACTED]

12. [REDACTED]

[REDACTED]

[REDACTED]

13. [REDACTED]

[REDACTED]

III. Timelines of [REDACTED]

14. Immediately after the preliminary injunction was issued against RaDaR 1.0 on December 27, 2023, I and others at NeoGenomics began brainstorming potential modifications to the RaDaR product that did not perform [REDACTED]

[REDACTED]

15. By the beginning of February 2024, we proposed a design for [REDACTED] February to March 2024, [REDACTED] Starting in March 2024, we began the feasibility stage of assay development.

16. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

17. [REDACTED]

[REDACTED]

18. [REDACTED]

[REDACTED]

² [REDACTED]

³ Natera and Dr. Metzker make several statements that are incorrect. Though I will not attempt to correct them all, Natera's statement that [REDACTED] is one such statement.

[REDACTED]

[REDACTED]

19. [REDACTED]

[REDACTED]

20. [REDACTED]

[REDACTED]

IV. Differences between [REDACTED]

21. As I discussed in my deposition, the primary differences between [REDACTED]

[REDACTED]

[REDACTED] Both of these changes consist of performing well-known laboratory techniques that have existed for decades. Ligation has been around since the 1960s, and scientists have been able to perform PCR [REDACTED]

[REDACTED] since PCR began in the 1980s. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

22. [REDACTED]

[REDACTED] I understand that both Natera and NeoGenomics agree that the claimed tagging must come before the claimed targeted amplification.⁶ For RaDaR 1.0, I understand that Natera has accused RaDaR 1.0 of “tagging with one or more universal tail adaptors” in [REDACTED] and “amplifying” in [REDACTED]

23. [REDACTED]

24. [REDACTED]

⁶ Dkt. 264-2, Natera Appeal Resp. Br. at 37 (“Claim 1 requires that DNA be ‘tagg[ed] in one step and then [amplified] in one or more subsequent steps.’”) (citing ’035 patent at 249:46-57); *see* Dkt. 280 at 4 (“The parties agree that ‘amplifying the tagged products’ is a separate step from ‘tagging isolated cell-free DNA with one or more universal tail adapters to generate tagged products.’”).

[REDACTED]

25. [REDACTED]

[REDACTED]

[REDACTED]

Q. Are there other differences between RaDaR Version 1.0

A. There are.

Q. What are they?

A. [REDACTED]

[REDACTED]

[REDACTED] (underline added).

26. As I discussed in my deposition, adjustments have been made to other steps in the workflow to accommodate these changes. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Neither of those adjustments affects the question of whether [REDACTED] infringes because none of the asserted claims require [REDACTED]

[REDACTED]

V. The Design of [REDACTED] is Fixed

27. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

28. In his declaration, Dr. Metzker provides a list of aspects of [REDACTED] he believes to be “material changes” that are “not yet defined” and therefore impact his ability to assess infringement of the asserted patents. I disagree and address each of those points below:

29. **The types of [REDACTED] that will be used.** Dr. Metzker points to a question in my deposition of [REDACTED]

[REDACTED] Metzker Decl. at ¶ 15. I disagree that the vendor that supplies [REDACTED] is relevant to the infringement inquiry. [REDACTED]

[REDACTED]

[REDACTED]

30. **The precise method of [REDACTED]** Dr. Metzker points to my deposition testimony that [REDACTED] Metzker Decl. at 14. By “format,” I was referring to the physical quantities ordered, for example the volumes of the tubes. I do not believe the form in which [REDACTED] is ordered is relevant to infringement. [REDACTED]

[REDACTED]

[REDACTED]

31.

[REDACTED] As I explained in my deposition, [REDACTED] the length of the primers will [REDACTED]

32.

[REDACTED] I do not believe the [REDACTED] is relevant to infringement. Nevertheless, I described the composition of the [REDACTED] in my deposition.⁹ [REDACTED]

33.

[REDACTED] I was not asked for [REDACTED] If I had been asked, I would have explained [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

34. Addition of intermediate steps related to [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

35. [REDACTED] As Dr. Metzker points out, I testified that

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] It is therefore

[REDACTED]

irrelevant to whether [REDACTED] infringes the asserted claims, [REDACTED]

36. I understand Natera has asserted that NeoGenomics' documents and witnesses did not identify the [REDACTED] I was not asked for the [REDACTED]

[REDACTED] If I had been asked, I would have explained [REDACTED]

37. [REDACTED]

[REDACTED] Both of those statements are inaccurate. I was not asked in my deposition [REDACTED]

[REDACTED] If I had been asked, I would have explained that [REDACTED]

38. I also understand my colleague Dr. Giovanni Marsico was directly asked and testified regarding [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

VI. Documents Provided Regarding [REDACTED]

39. I understand Natera has accused NeoGenomics of waiting to disclose evidence about [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 08Aug2024

Tim Forshew

Tim Forshew, Ph. D.